GLYTONE

EXCLUSIVE TO PHYSICIANS

Form B

UNEXPECTED REACTIONS FORM

☐ Initial report ☐ Follow-up ☐ Final report

Reporter's Name	Address	
Phone	Fax	E-mail

PATIENT DATA AND MEDICAL HISTORY

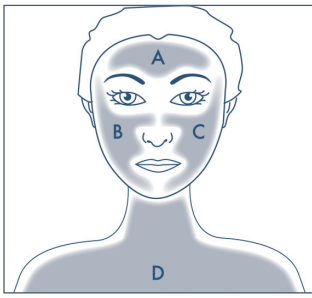
Patients first and last name initials	Age	Weight	Sex: M F	Ethnic Origin: Hispanic Asian/Pacific Islander Caucasian African American Other

Diabetic? ☐ YES ☐ NO

Chronic disease? ☐ YES ☐ NO If yes, specify _____

Allergies? ☐ YES ☐ NO If yes, specify _____

TREATMENT



Name of Peel Applied	Date of Treatment
Treated Area (A, B, C, D and/or hands and /or back and/or different skin areas):	
Number of Coats (circle): 1 2 3	Total time (minutes) 1 2 3 4 5 6+
Area affected by adverse reaction:	

Previous Treatments (in last 6 months)

- None ☐
- Peel treatments ☐
- Botox ☐
- Other Injection Therapy ☐
- Laser ☐
- Other:

OUTCOME

Description of outcome – symptoms, physician examination, lab data, etc.

Symptoms	Cutaneous Area
Erythema	A B C D
Swelling	A B C D
Pain	A B C D
Redness	A B C D
Hyperpigmentation	A B C D
Ulcers	A B C D
Blisters	A B C D
Burns	A B C D
Others (specify):	A B C D

Photo documentation ☐ YES ☐ NO

Time to onset of symptoms: When was it first used and when was the reaction seen? Minutes, hours, days? _____

How did the reaction evolve? Spontaneous, small red area after hours/days/weeks, itching, blistering, immediate overreaction, etc. _____

_____

How often was it used? One treatment? Two? _____

Where was it used? Spa, office? At home use? _____

Concomitant use: Was it used with or in conjunction/along side other products? ☐ YES ☐ NO If yes, drugs? OTC drugs? explain _____

_____

Did patient recently stop taking another cosmetic/OTC/drug? ☐ YES ☐ NO If yes, name/type of product _____

How long were the lesions in question present?_____

Did you treat the lesion with any drugs or other products? If so, please disclose._____

Describe the frequency of treatment?_____

Did the patient use any topical retinoids (e.g. Tazorac, Retinol) within the past 10 days? ☐ YES ☐ NO

Has the patient used Isotretinoin (e.g. Accutane) within the past 6 months? ☐ YES ☐ NO

FAX THIS FORM TO (973) 898-0420 ATTN: Regulatory Affairs Dept

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TREATMENT OF OUTCOME

Treatment used by physician/other to ameliorate/repair/fix the reaction? _____

Does the physician have a diagnosis or suggestions for what went wrong? _____

CLASSIFICATION OF INCIDENT

Was there a death? ☐ YES ☐ NO

Hospitalization? ☐ YES ☐ NO

Surgery required? ☐ YES ☐ NO

Disability or other permanent damage? ☐ YES ☐ NO

Permanent injury? ☐ YES ☐ NO If yes, get description. _____

Was the unexpected event one of the expected or listed side effects? ☐ YES ☐ NO

Were the instructions for use followed? ☐ YES ☐ NO If no, what deviations? _____

Was the product maintained/stored within the temperature range of "41°F/5°C and 77°F/25°C"? ☐ YES ☐ NO

Profession of person who applied the treatment (physician, technician) _____

How long did the person apply the product to the skin prior to neutralization? Answer in total minutes for the peel active ingredient [acid] on the skin:

_____

Was the treatment a multilayer/multi-product application or multiple layers of the same product used? ☐ YES ☐ NO

Was this treatment part of a series of treatments? ☐ YES ☐ NO If yes, how many treatments were given? _____

Was the patient pregnant or breastfeeding? ☐ YES ☐ NO

Did the patient have a history of scarring, keloids or other skin issues? ☐ YES ☐ NO

Reporter signature	Date of the report

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